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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,151	11/25/2005	Yuwan Wang	P050002US	1882

50163 7590 08/21/2008

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EXAMINER	
SCHLIENTZ, NATHAN W	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
08/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/558,151	WANG ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-29* is/are pending in the application.

4a) Of the above claim(s) *27-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-26* is/are rejected.

7)☒ Claim(s) *18-20,22-24 and 26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of the species avermectins in the reply filed on 05 May 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Status of Claims

Claims 1-15 were cancelled and claims 16-29 were newly added in a preliminary amendment filed 25 November 2005. Claims 27-29 are withdrawn from further consideration, thus, claims 16-26 are examined herein on the merits for patentability. No claim is allowed at this time.

Claim Objections

1. Claims 18-20 and 26 are objected to because of the following informalities: the instant claims have Markush groups listed in improper Markush format, as well as misspelling the word "parasiticide" in claim 19 and "larger" in claims 21 and 26. For instance, claim 18 should be amended to read, "said adjuvant is selected from the

group consisting of a non-ionic surfactant, suspending agent, material for sustained release, antioxidant[,] and local analgesics." Claim 19 should be amended to read, "said therapeutic drug or active ingredient is selected from the group consisting of an avermectin, a NSAID, a parasiticide ~~paraiticide~~ ...". Claim 20 should be amended to read, "said NSAID is selected from the group consisting of COX-2 inhibitor ...", "said antibiotic is selected from the group consisting of cephalosporin ...", and "said sex hormone is selected from the group consisting of estrogen, progesterone, and ~~or~~ androgen." Claim 21 should be amended to read, "polyethylene glycol with molecular weight larger ~~lager~~ than 1000, gelatin, gum Arabic, ethylcellulose, and polyvinyl butyral." Claim 26 should be amended to read, "said carrier is selected from the group consisting of ethylcellulose, hydrogenated castor oil, PVP, and ~~or~~ PEG with MW larger ~~lager~~ than 1000." Appropriate correction is required.

2. Claims 22, 24 and 26 are objected to because of the following informalities: they do not end with a period. See MPEP 608.01(m). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26 recites the limitation "said carrier" in the second line

of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 26 is dependent from claim 16, which does not claim a carrier.

2. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, it is unclear what is meant by the adjuvants "Paregal" and "OP". It is believed by the examiner that OP is octylphenoxy (i.e. *p*-(1,1,3,3,-tetramethylbutyl)phenyl polyethylene glycol ether). However, further clarification is requested. Also, for clarity, the examiner recommends replacing Myrjs with polyoxyethylene (POE) fatty acid esters, and Brijs with POE fatty alcohol ethers.

3. Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, it is believed by the examiner that BHT is butylated hydroxytoluene, and BHA is butylated hydroxyanisole. Also, the acronym "PG" is commonly used in the art to represent propylene glycol. However, it is believed that Applicant intended "PG" to represent propyl gallate, because propyl gallate is commonly used in conjunction with BHT and BHA in improving the storage life of lard, tallow oils, poultry fat, and various other fats and oils (Tenox Antioxidant, retrieved from the internet at http://findarticles.com/p/articles/mi_m3289/is_2_172/ai_97728682 on 19 March 2008). Further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 16-19, 21 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamahira et al. (US 5,385,738).

Yamahira et al. disclose a sustained release injection formulation comprising an active ingredient and a pharmaceutically acceptable biodegradable carrier (i.e. gelatin) in a viscous solvent (i.e. silicone oil) for injection (Abstract; and col. 1, ll. 10-17 and 36-42). Yamahira et al. disclose indomethacin, various bio-hormones, and antibiotics are suitable pharmaceutical active ingredients for use in their invention (col. 2, ll. 18-54), wherein indomethacin is usually contained in an amount of 0.5 to 500 mg, preferably 1 to 200 mg, per dosage unit, or 0.005 to 10 mg per 1 mg of the carrier (col. 3, ll. 39-54). Also, Yamahira et al. disclose that other conventional pharmaceutically acceptable additives may be added, such as local anesthetic agents and some agents for aiding release-sustaining properties of the active ingredient, such as ethylcellulose, PVP and PEG (col. 4, ll. 43-59).

2. Claims 16-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Manetta et al. (US 2006/0100165).

Manetta et al. disclose a topical pharmaceutical emulsion comprising ivermectin, ceteareth-20, sorbitan monostearate, and dimethicone 200 20 cs (claims 15, 16, 20 and 21). It is noted that the recitation of the intended use "sustained release injection" has not been given patentable weight to distinguish over Manetta et al. because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since Manetta et al. discloses compositions that has all the ingredients as instant claimed, the compositions anticipate said claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 16-21 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lo et al. (Veterinary Research Communications, 1985) in view of Yamahira et al. (US 5,385,738).

Applicant claims:

Applicants claim a sustained release injection formulation comprising an avermectin as a therapeutic drug or active agent and dimethicone as dispersing medium.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Lo et al. teach a controlled release formulation comprising ivermectin, propylene glycol and glycerol, wherein the formulation is given as a single I.V. bolus or subcutaneously (Abstract and pg. 5, "Intravenous Dosing" and "Subcutaneous Administration").

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Lo et al. do not teach the controlled release ivermectin formulation comprising dimethicone, as instantly claimed. However, Yamahira et al. teach sustained release injection formulations comprising an active agent in a viscous solvent, wherein conventional solvents for injection include propylene glycol and silicone oil (Abstract and

col. 3, ll. 30-34). Yamahira et al. also teach that other conventionally pharmaceutically acceptable additives may be added, such as local anesthetic agents and some agents for aiding release-sustaining properties of the active ingredient, such as ethylcellulose, PVP and PEG (col. 4, ll. 43-59). Yamahira et al. further teach that the sustained release injection preparation is prepared by pulverizing the active ingredient and carrier into a particle size of 0.1 to 1000 μm, then suspending the powder in a viscous solvent for injection (col. 3, l. 55 through col. 5, l. 22).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use silicone oil in the place of propylene glycol in the controlled release injection formulations of Lo et al., because Yamahira et al. teach that silicone oil and propylene glycol are conventional viscous solvents used in sustained release injection formulations.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616